Appendix A

This summary of 510 (k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Name, Address, Phone and Fax number of the Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054
Telephone 408-845-1910
Fax: 408-845-1901

Contact Person: Debbie Cogan, Regulatory Affairs Associate

Date Prepared: May 23, 2002

Device Name: Trade Name: Syncrus™ Internal Cardioversion System

Product code: NHW

Device name: Electrode, pacing and cardioversion, temporary, epicardial

Regulation number: 870.3680

Class: II (two)

Regulation name: Pacemaker electrode, temporary

Device Description: The Syncrus Heart Wires and Connectors are used for atrial and ventricular pacing and electrocardiogram sensing to diagnosis and treat atrial (type I) flutter and some forms of tachycardia. The wires are also used to treat post-operative arrhythmias, particularly atrial fibrillation, when used in conjunction with the Syncrus Cardioversion

Extension Cable and Syncrus External Defibrillator Interface Module (EDIM). The EDIM is a passive device. The EDIM when used with a compatible external monophasic defibrillator reduces the energy to approximately 3% and delivers the low-energy cardioversion shock directly to the atria. The cardioversion is achieved by delivering a synchronized electrical pulse of approximately 11.1 Joules or less to the atrial chambers of the heart. There are three types of Heart Wires:

- A tripolar atrial wire, capable of pacing and sensing, and cardioversion, when used in conjunction with the unipolar wire.
- A unipolar atrial wire, capable of cardioversion when used in conjunction with the cardioversion electrode on the tripolar wire.
- A bipolar ventricular wire, capable of pacing and sensing.

The wires are comprised of curved needle(s), attached to lead(s) on the proximal end. The wires are insulated for long length. A straight needle is attached to the leads on the distal end of the wires. Cardioversion connectors are provided that attach to the appropriate heart wire leads. Pacing connector pins are pre-assembled onto the appropriate heart wire leads.

The Syncrus Heart Wires are intended to be affixed to the surfaces of their respective heart chambers, during or immediately following open-heart surgery, before the median sternotomy is closed. Temporary pacing heart wires are routinely implanted in a similar manner. The unipolar atrial wire is placed on the left atrium, the tripolar atrial wire is placed on the right atrium, and the bipolar ventricular wire is placed on either ventricle. If all of the Heart Wires are implanted, the atrial and ventricular temporary sensing and pacing ability can be used, and only if the patient develops post-operative AF would the cardioversion feature be used. Both the unipolar atrial wire and the tripolar atrial wires are required in order to perform a cardioversion. When only the capability to treat post-operative AF is desired, the ventricular wire is not required.

When the pacing feature is used, the pacing lead is inserted into the myocardial tissue of the atrium using the curved needles. Location and pattern of the lead is not critical, as the lead simply requires tissue contact.

The "bullet" (define) on the ground wire is then pulled through the hole formed by the curved needle, and is thus buried in the myocardial wall.

Intended Use: The Guidant Syncrus™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

Substantial Equivalence: The Guidant Syncrus System is substantially equivalent to the Medtronic Pacing & Sensing Wires (Model 6500), the Physio-Control Internal Paddles, which are an accessory to the Physio-Control LifePak 9 External Defibrillator and the R2 Cable Adapter. The Medtronic Pacing & Sensing Wires have received clearance for temporary operative/post-operative cardiac pacing and intracardiac ECG monitoring under K944957. The Physio-Control LifePak 9 External Defibrillator, including the internal paddle accessory, has received clearance for use in the diagnosis and treatment of cardiac dysrhythmias under K935674. The R2 Cable Adapter has received clearance for use in defibrillation and cardioversion.under K800937.

Device Testing Results and Conclusions: All necessary testing was performed on the Guidant Syncrus System to ensure that the system is substantially equivalent to the predicate devices and to ensure that the device is safe and effective when performing temporary pacing and sensing and functioning as a defibrillator interface to deliver low energy electrical shock in post-operative cardiac surgery patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2002

Ms. Debbie Cogan
Regulatory Affairs Associate
Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054-2087

Re: K020701
Trade Name: Syncrus Internal Cardioversion System
Regulation Number: 21 CFR 870.3680
Regulation Name: Temporary Epicardial Pacing and Cardioversion Electrode
Regulatory Class: Class II (two)
Product Code: NHW
Dated: March 1, 2002
Received: March 4, 2002

Dear Ms. Cogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 18. INDICATIONS FOR USE STATEMENT

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K K020701

Device Name: Guidant Syncrus™ Internal Cardioversion System

Indications For Use: The Guidant Syncrus™ Internal Cardioversion System is indicated for use in post-operative cardiac surgery patients who require temporary atrial or ventricular pacing/sensing and/or atrial cardioversion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020701
Elisa Mallis